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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,036	02/05/2002	Ole Thastrup	3759-0120P	3012

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EXAMINER

BURKHART, MICHAEL D

ART UNIT PAPER NUMBER

1633

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/072,036	Applicant(s) THASTRUP ET AL.	
	Examiner Michael D. Burkhart	Art Unit 1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 01 June 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): USC 112 2nd ¶ rejection of claim 46.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 44-54.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See continuation sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
 13. ☐ Other: _____.

Continuation sheet

11. Regarding the Double Patenting rejection, applicants essentially argue that: 1) the rejection of the instant claims under Double Patenting and USC 102(b) is seemingly inconsistent; 2) the present specification clearly indicates that a "subunit of a component" is distinct from a "component", and point to a particular phrase wherein a distinction is allegedly made between a "protein kinase" and a "subunit thereof"; 3) a "component" is a fully functional protein whereas a "subunit of a component" is a part of a heteropolymeric protein; 4) subunits may be shared by more than one protein, and redistribution of such subunits may differ, leading to the study of different mechanisms; 5) only the choice of a subunit uniquely tied to a component would provide the same result as using the full-length gene.

Regarding 1), applicants fail to point out what is inconsistent about applying Double Patenting and USC 102(b) rejections to the same claims. The 102(b) rejection calls into question the patentability of the '021 claims, hence the previous Office Action has been signed by a primary examiner and a director of Technology Center 1600, according to Office policy. Regarding 2) and 3), there is no definition of "subunit" or "component" in the instant application, and merely mentioning that protein kinases and subunits thereof (e.g. in the section "Background of the Invention", fifth ¶, as cited by applicants) may be used in the claimed methods does not provide any such definition. As explained in the previous Office Action, the problem is that a "component", even if treated as a "fully functional protein", can still be considered a subunit. This is because "fully functional proteins" involved in intracellular pathways bind to and modify other "fully functional proteins", the complex of said "fully functional proteins" being a "component" of the pathway and the individual proteins "subunits" (this also applies to 3) - 5)

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above). One example is the NF- κ B and I κ B proteins listed in the '021 abstract as examples of components of intracellular pathways. These proteins bind to form a multimeric complex in the cytoplasm of cells, in which case NF- κ B and I κ B are each considered subunits of said complex. Thus, they meet the definition of a subunit, and seemingly also meet applicants' definition of a "fully functional protein", i.e. a component. Thus, it is still considered that the '021 claims and the instant claims are no different in scope.

Regarding the USC 102(b) rejection, applicants argue that Carey et al do not disclose step (b) of the presently claimed methods, i.e. "...to be screened for biological function or biological effect." Applicants argue that characterization of dexamethasone is not to be considered such a substance because its effect was already known.

Such is not persuasive. First, the limitation "...to be screened for biological function or biological effect" is merely an intended use limitation and as such does not impart patentable weight to the method. One of skill in the art could have used the methods of Carey with any chosen substance and determined an effect. Secondly, it is clear that Carey did use the method to determine the effect of dexamethasone on the translocation GR-GFP fusion protein from the cytoplasm into the nucleus (see abstract and Fig. 1). Absent evidence to the contrary, this is a biological function and a biological effect, regardless if it was known in the art or not.

Regarding the objection to claim 48, the amendment has not changed the scope of the term "chemical substance", as the term "chemical compound" is synonymous in light of the

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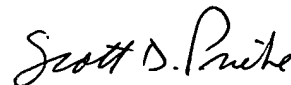
specification, which does not provide a definition for either term. A protein is still considered to be a chemical compound because it is made up of atoms, like any other chemical compound.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
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SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER